

Medical Countermeasure Award: The PRISM Office awarded Ology Bioservices a \$130.3 million, 10-year contract, entitled, "Development and Utilization of a Monoclonal Antibody Platform Prototype for Development of Monoclonal Antibodies as Medical Countermeasures Against Threats of Interest." This program is part of PRISM's Advanced Development and Manufacturing of Antibody Technologies (ADAMANT) platform concept, which is intended to explore how monoclonal antibodies can be used as next-generation medical countermeasures against chemical and biological threats.

Technology Award: PRISM also awarded Ology Bioservices a \$5.1 million, 30-month contract entitled, "Developing, Establishing and Exercising Plasmid DNA Manufacturing Capabilities at the DOD Advanced Development and Manufacturing Facility."

Under this program, Ology Bioservices will develop and deliver a prototype manufacturing platform for the CGMP production of nucleic acids, primarily plasmid DNA for use as both Drug Substance and high-quality intermediate. Plasmid DNA is important, primarily for its use in DNA vaccines and gene therapy. The aim of the project is to more rapidly and efficiently deliver biodefense medical countermeasures to warfighters, with reduced developmental risk.

"To date, no one has successfully used monoclonal antibodies against *Y. pestis* as a treatment for Plague in humans," said Dr. Robert V. House, Senior Vice President, Government Contracts at Ology Bioservices. "This multiyear program, which will encompass solutions for discovery/design, manufacturing, testing, quality, regulatory strategy and program management, gives Ology Bioservices the unique opportunity to make meaningful strides in this arena. We have assembled a world-class team to assist us in this effort including the Duke Human Vaccine Institute, Just Biotherapeutics, Inc., Mapp Biopharmaceutical, Inc., the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Cato Research, Certara and Battelle."



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Ology Bioservices Enters Phase 1 Clinical Trial for Anti-COVID-19 Monoclonal Antibodies

12/17/2020

Ology Bioservices Inc. (Ology Bio), a biologics contract development and manufacturing organization (CDMO), announced today that it has begun dosing volunteers in a Phase 1 clinical trial with ADM03820, a cocktail of anti-SARS-CoV-2 monoclonal antibodies.

Resilience Subsidiary Ology Bioservices Awarded Contract Worth Up To \$250 Million from U.S. Department of Defense for Botulinum Neurotoxin Treatment

2/9/2022

National Resilience, Inc. today announced the U.S. Department of Defense (DOD) has awarded Ology Bioservices, Inc. (Ology), a wholly owned subsidiary of Resilience, a contract valued as much as \$250 million for manufacturing development of a monoclonal antibody as a medical countermeasure (MCM) to botulinum neurotoxin.

INOVIO to Develop DNA-encoded Monoclonal Antibody (dMAb®) Candidates to Treat COVID-19 with Funding from the Defense Advanced Research Projects Agency (DARPA)

12/15/2020

- DARPA to fund innovative public-private partnership between INOVIO, The Wistar Institute, AstraZeneca, the University of Pennsylvania and Indiana University
- \$37.6 million grant from DARPA will leverage AstraZeneca's monoclonal antibody and INOVIO's DNA-encoded monoclonal antibody (dMAb®) technologies in the fight against COVID-19

Ology Bioservices Awarded \$37 Million by Department of Defense for Advanced Development of Anti-COVID-19 Monoclonal Antibody Cocktail

11/23/2020

Ology Bioservices Inc. (Ology Bio), a biologics contract development and manufacturing organization (CDMO), announced today that the Department of Defense (DOD) has awarded the company with an agreement valued at \$37 million.

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Department of Defense Awards Ology Bioservices Contract to Manufacture and Test Novel Live Attenuated Tularemia Vaccine Candidate

10/27/2020

Ology Bioservices Inc. (Ology Bio), a biologics contract development and manufacturing organization (CDMO), announced today that the Department of Defense (DOD), through the Joint Science and Technology Office of the Defense Threat Reduction Agency (DTRA), has awarded the company with a contract to manufacture a novel live attenuated tularemia vaccine. The contract value is \$6.3 million. The vaccine candidate ATI-1701

Resilience Inc acquired Ology Bioservices on April 12, 2021

The terms of the deal were not disclosed

Ology Bioservices is a biologic drug substance manufacturing company that specializes in developing and manufacturing drugs and biologics for commercial customers as well as the US government. The acquisition provides Resilience with 300 skilled employees as well as more than 200,000 square feet of infrastructure that will provide services for Resilience's customers, including regulatory support from preclinical through licensure, clinical trial operational support and bioanalytical testing, as well as cGMP manufacturing up to Biosafety Level 3 (BSL3)

≡ News • Aug 17, 2018

[BioSpace – Ology Bioservices Wins \\$8.4 Million Defense Department Award to Produce Anti-Ebola Medical Countermeasure](#)

[Mapp Biopharmaceutical](#) is an American biotechnology company that develops novel pharmaceuticals for the prevention and treatment of infectious diseases, focusing on global health and biodefense ¹. The company was founded in 2003 by [Larry Zeitlin](#) and [Kevin Whaley](#) and is based in [San Diego, California](#) ² ³. Mapp Biopharmaceutical is responsible for the research and development of [ZMapp](#), a drug which is still under development and comprises three humanized monoclonal antibodies used as a treatment for Ebola virus disease ². The company collaborates with other organizations such as [LeafBio](#), [Defyrus Inc.](#), the [U.S. government](#), and the [Public Health Agency](#) of Canada to develop its products ². Mapp Biopharmaceutical has also received funding from the Biomedical Advanced Research and Development Authority (BARDA) to advance the development of therapeutics for Marburg virus disease, Sudan ebolavirus, and Botulinum Neurotoxin ¹. The company has around 70 employees ⁴.

[Mapp Biopharmaceutical](#) was awarded \$109.8 million by the [U.S. government](#) for the advanced development and potential purchase of [MBP134](#), a monoclonal antibody cocktail ¹. MBP134 has set new benchmarks in both antiviral breadth and therapeutic efficacy ². Mapp Biopharmaceutical is developing MBP134 ² and is a biotechnology company that develops novel pharmaceuticals for the prevention and treatment of infectious diseases, focusing on unmet needs in global health and biodefense ³ ⁴ ⁵.

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NIAID awards \$22 million grant to develop antibody-based therapies against lethal viruses

[Download PDF Copy](#)*Reviewed by James Ives, M.Psych. (Editor)*

Apr 4 2019

The National Institute of Allergy and Infectious Diseases (NIAID) has awarded an international consortium led by Albert Einstein College of Medicine, part of Montefiore, a five-year, \$22 million grant to develop antibody-based therapies against four highly lethal viruses for which there are no approved vaccines or treatments.

The viruses are the tick-borne Crimean-Congo hemorrhagic fever virus (CCHFV) and three hantaviruses, which are spread by rodents: Andes virus (ANDV), Sin Nombre virus (SNV), and Puumala virus (PUUV). The NIAID has designated all

The project, called the Prometheus Center for Excellence in Translational Research (Prometheus), focuses on viruses that spread from animals to people. It builds on a 2017 study involving ebolaviruses, believed to spread to people from fruit bats or primates. In addition to Einstein, the participating institutions leading the project are the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Mapp Biopharmaceutical, Inc., The University of Texas at Austin, and Adimab, LLC, a biotech company.

Building on Ebola Research

Einstein, USAMRIID, Mapp Biopharmaceutical, and Adimab scientists were part of a team that analyzed 349 natural human antibodies against ebolavirus in the blood of a survivor of the 2013-16 West African Ebola outbreak. After finding that two of the antibodies potently neutralized all six known ebolaviruses in tissue culture, the investigators developed MBP134, a cocktail of two fully human monoclonal antibodies that protected animals against all three major disease-causing ebolaviruses. (Monoclonal antibodies, or mAbs, are antibodies made by identical immune cells that are all clones of a unique parent cell.) The current leading ebola therapy, a mAb cocktail called ZMapp, is effective against only a single ebolavirus.

The second project will be co-led by Zachary Bornholdt, Ph.D., director of antibody discovery at Mapp Biopharmaceuticals and Jason McLellan, Ph.D., associate professor of molecular biosciences at The University of Texas at Austin. This project will focus on engineering viral antigens to be used for antibody discovery, structural studies to define the antibody epitopes (i.e., the targets to which antibodies bind), and engineering antibodies to maximize their antiviral effectiveness in animals and humans. Other Prometheus components, led by Andrew Herbert, Ph.D., senior research scientist for the Geneva Foundation at USAMRIID, and Larry Zeitlin, Ph.D., chief executive

Larry Zeitlin, Ph.D., chief executive officer of Mapp Biopharmaceutical, will focus on testing the antibodies for their effectiveness in animal models and the preclinical development of lead antibodies.



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Einstein will serve as the lead and coordinating institution for Prometheus and also will co-lead one of the projects with John Dye, Ph.D., chief of viral immunology at USAMRIID: identifying the most promising antiviral antibodies and studying how they block the viruses from entering host cells

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Ology Bioservices, Vanderbilt University Medical Center to Develop, Manufacture Monoconal Antibody for Treatment, Prevention of Infection With COVID-19 Virus for Department of Defense

3/23/2020

The Department of Defense awarded a contract valued at \$14 million with Ology Bioservices Inc., a biologics contract development and manufacturing organization, to develop and manufacture a monoclonal antibody for treatment and prevention of infection with the COVID-19 virus.

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Chem-Bio Defense Program Eases Path for Industry

3/30/2018

By Tim Belski, Lt. Col. Matthew Clark and Hannah Feldman

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In a 2016 congressional hearing, former Director of National Intelligence James Clapper stated that chemical, biological, radiological, and nuclear weapons and emerging infectious diseases constitute a major threat to the security of the United States.

Medical countermeasure systems is a joint project management office located at Fort Detrick in Frederick, Maryland, and facilitates the advanced development and fielding of these medical countermeasures.

In order to streamline the acquisition process that provides critical medical countermeasure products to the warfighter, the two offices are employing a new “agile medical paradigm,” or AMP. Its mission is to decrease risk, address a broader threat environment, and enable a rapid response capability to future threats.

The medical countermeasures system office is overcoming these hurdles by utilizing “other transaction agreements” — also known as OTA — as set forth in U.S. law in 10 USC 2371b. Other transactions are legally binding instruments that are used to engage industry and academia on a broad range of research and prototype projects. The mechanism provides an opportunity for nontraditional defense contractors to partner and address important capability requirements across the federal government.

Employing OTAs allows for speed, adaptability and accessibility in providing prototypes and medical countermeasures, without having to meet the many statutory requirements governed by the FAR. In short, this authority is designed to stimulate innovation.

As a part of this effort, the office has partnered with Advanced Technology International to create the Medical CBRN Defense Consortium. Now with over 130 members — including prominent industry, academic and nonprofit partners — the consortium facilitates a flexible arrangement with the Defense Department to accelerate medical countermeasure development.

The office identifies requirements through Army Contracting Command-New Jersey and solicits proposals for prototype projects from consortium members. By working with industry and academic leaders, the office streamlines the process for providing new medical products to the warfighter.

Members receive benefits such as networking opportunities with other consortium members and government stakeholders; providing visibility into government needs and priorities; and expanding their market by creating a channel for small companies and nontraditional technology providers to engage in the federal acquisition process.

The consortium is another tool in the medical countermeasures systems toolbox that improves acquisition and incentive strategies.

Through a competitive source-selection process, the office awarded Emergent BioSolutions a five-year agreement through the consortium to develop the novel multi-drug autoinjector for nerve agent antidote delivery. The office is leveraging partnerships with other consortium members such as SHL Pharma Inc., Battelle and Ology Bioservices Inc. in order to develop autoinjectors to deliver nerve agent treatments.

By examining past experience and lessons learned from medical countermeasure development, the joint program office is looking toward the future by utilizing the other transaction authority to improve and enhance the ability to treat and protect servicemembers from the effects of CBRN agents and emerging infectious diseases.

Included in the initiative is the Advanced Development and Manufacturing facility in Alachua, Florida, which provides the Defense Department with a dedicated manufacturing capability, particularly for niche military pharmaceutical products.

A world-class facility, it utilizes state-of-the-art single use technology, and contains two current “good manufacturing practices” compliant manufacturing suites. The facility is biological safety level 3 capable, which allows staff to work with microbes that can cause serious and potentially lethal disease via inhalation. It facilitates development and manufacturing of medical countermeasures that will protect and treat servicemembers who may be exposed to biological or chemical weapons, toxins or infectious diseases, as well as radiological or nuclear events.

With guidance from the White House, the medical countermeasures system office “determined that a successful facility would leverage the development expertise of large biopharmaceutical corporations while retaining the innovative spark possessed by many smaller biotech companies,” said Tim Belski, joint product director for advanced development and manufacturing capabilities at the Pentagon.

“This meant that any business arrangement had to be attractive to private industry partners seeking a return on their investments, be able to support DoD surges in the event of an emergency, and support DoD’s manufacturing of medical countermeasures at smaller volumes than typical commercial levels,” Belski added.

Chartered in October, the platforms for rapid integrated solutions for medical countermeasures (PRISM) joint product lead aims to accelerate medical countermeasure delivery to the warfighter through the development and implementation of platform systems. PRISM is a part of a translational team with the Defense Threat Reduction Agency's joint science and technology office.

PRISM will establish a toolbox of platform systems that can be used to counter a variety of threat agents using standardized discovery, design, manufacturing and testing processes to streamline generation of a portfolio of medical countermeasure candidates. PRISM will also adapt some of these platform systems to support a rapid response capability needed to respond to emerging and novel threats.

“Advanced development and manufacturing of antibody technologies” is the first platform being implemented under PRISM. It is a monoclonal antibody platform that provides a capability to respond to recognized, emerging and engineered threats; provides interim fielding candidates early in development; and cost effectively brings antibody countermeasures from discovery to licensure and fielding.

The platform is currently being used to develop a botulinum toxin therapeutic and prophylactic medical countermeasure at the Advanced Development and Manufacturing facility.